



56330-A/JPW/PJP

**APPARATUS AND METHOD TO TREAT A DISEASE PROCESS IN A
LUMINAL STRUCTURE**

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This application is a continuation-in-part of application Serial No. 09/271,063, filed March 17, 1999, incorporated by reference herein, now U.S. Patent No. 6,200,256.

10 **BACKGROUND OF THE INVENTION**

15 The present invention relates to an apparatus and a method to treat a disease process in a luminal structure. Such a structure includes, but is not limited to, veins, arteries, bypass graft prostheses, the gastrointestinal (GI) tract, the biliary tract, the genitourinary (GU) tract, and the respiratory tract (e.g. the tracheobronchial tree).

20 Within this application several publications are referenced by Arabic numerals within parentheses. Full citations for these and other publications may be found at the end of the specification immediately preceding the claims. The disclosures of all of these publications in their entireties are hereby incorporated by reference into this application in order to more fully describe the state of the art to which this invention pertains.

30 Percutaneous transluminal coronary angioplasty ("PCTA") is commonly used in the treatment of coronary artery obstruction, with over 400,000 procedures performed annually. The process involves the insertion of balloon catheters through the femoral artery to the targeted coronary artery. Injection of radio-opaque contrast into the proximal coronary artery allows fluoroscopic localization of stenosed coronary segments. Balloon catheters are advanced to the site of stenosis over extremely thin guide wires to position the catheter at the point of occlusion. The distal end of the catheter contains a balloon which is inflated for 2-4 minutes to the full diameter of the occluded artery, decreasing the blockage and improving blood flow.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

- 5 According to one aspect of the present invention, a tube segment is provided for treating a disease process in a luminal structure. The tube segment includes radioactive material for delivering radiation for treating a disease process, and is adapted to be carried by a balloon catheter for insertion in the luminal structure.
- 10 The radioactive material may be in the form of a coating.
- The tube segment may comprise a mixture of radioactive material and non-radioactive material.
- 15 The tube segment may comprise non-radioactive material into which is adsorbed radioactive material.
- The tube segment may be made of expandable and collapsible material, whereby its shape is determined by the shape of the balloon.
- 20 The tube segment may be located in the interior of or on the exterior of the balloon. If exterior, the tube segment has adhesive material on its inner surface, for adhering the tube segment to a balloon.
- 25 If expandable, the radioactive material is present in a predetermined dosage per surface area of the tube segment when the tube segment is in an unexpanded state, wherein the dosage changes as the tube segment is inflated.
- 30 The sleeve may be expandable in a range of sizes.
- 35 According to another form of the invention, an apparatus for treating a disease process in a luminal structure is provided, comprising a balloon catheter having an inflatable balloon and a tube segment adapted to be carried by and cover said balloon. The tube segment includes
- 40 radioactive material.